REMARKS

Claims 22-42 are pending in the instant application. Claims 27, 23, 27, 29, 31, 34, 36 and 38-42 are amended. Claims 1-21 have been cancelled previously. Claims 22-42 generally correspond to claims 1-21 as originally filed. No new matter is submitted. Accordingly, entry and consideration of the Amendment is respectfully requested.

This Amendment is submitted in response to the Final Office Action, mailed March 17, 2006, to request reconsideration of the rejection of claims 22-42 (as best understood based on the Office Action). In the event the Examiner determines that the foregoing amendments do not place this application in condition for allowance, entry thereof is nevertheless respectfully requested in order to place the claims in better form for appeal, should an appeal be pursued in this matter.

The Office Action characterizes claims 22-39 as having replaced previously cancelled claims 1-21. Applicants clarify herein that claims 22-42 (emphasis added) have replaced the previously cancelled claims 1-21.

Claims 40-42 are nowhere rejected or addressed in the Office Action, while cancelled claims 2-5 and 10-21 are rejected based on art or double patenting rationales set forth at pages 4-5 of the Office Action. To the extent that cancelled claims 2-5 and 10-21 respectively correspond to pending claims 23-26 and 31-42, the rejections of claims 2-5 and 10-21 set forth in the Office Action are understood to be directed to the respective corresponding pending claims. Clarification of the intended treatment of claims 22-42 in view of the characterization of the claims in the Office Action is respectfully requested.

With respect to the non-statutory double patenting rejection of claims 2-5 and 10-21 at page 5 of the Office Action (understood to refer to respective corresponding pending claims 23-

26 and 31-42), the Terminal Disclaimer and accompanying fee filed November 2, 2004 is indicated on the USPTO PRIVATE PAIR system as entered and "APPROVED BY V. IRBY – FEE PAID" (see copy of USPTO PRIVATE PAIR page attached). Accordingly, acknowledgment of the entry and approval of the Terminal Disclaimer, and withdrawal of the Double Patenting rejection of claims 2-5 and 10-31 (corresponding to pending claims 23-26 and 31-42) based thereon, is respectfully requested.

At pages 3-4 of the Office Action, claims 22-39 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Derek Gordon 1997 (Publication: "Too Big a Heart" in which a cardiac reduction procedure known as the "Batista procedure", based on the theories and practices of Dr. Randas Jose Vilela Batista in Brazil, is discussed) (hereafter "Gordon") in view of U.S. Patent No. 5,613,302 to Berman (hereafter "Berman") and/or either of U.S. Patent No. 4,624,671 to Kress (hereafter "Kress") or U.S. Patent No. 5,814,098 to Hinnenkamp, et al. (hereafter "Hinnenkamp"). The rejection is respectfully traversed.

Applicants' independent claims 22, 31 and 38 each recite a method of reshaping a patient's heart. In particular, claim 22 recites a method of reshaping a patient's heart comprising, *inter alia*, gauging a size of a left ventricle, determining an amount by which the left ventricle should be reduced from the gauging of its size, and reducing a dimension of the left ventricle in accordance with the determined amount. Claim 31 recites a method of reshaping a patient's heart comprising, *inter alia*, introducing an expansible member into a left ventricle of the patient's heart, expanding the expansible member within the left ventricle, and reducing a volume of the left ventricle by an amount based upon the expanded volume of the expansible member. Claim 38 recites a method of reshaping a patient's heart comprising, *inter alia*, encircling the heart with an adjustable length band, determining a size of a left ventricle with

reference to a length of the band, and reducing a volume of the left ventricle based upon the determined size of the left ventricle. The various methods of reshaping a patient's heart recited in independent claims 22, 31 and 38 are entitled to a priority date at least as early as the July 23, 1996 filing date of U.S. Patent No. 6,125,852 (U.S. Patent Application Serial No. 08/685,262), as agreed in the Interview held December 8, 2005.

Gordon, a July, 1997 internet publication, discloses very generally the cardiac reduction procedure (the "Batista procedure") that excises chunks of muscle from the heart in order to more nearly approximate a muscle mass to heart diameter proportion characterized as "a perfect proportion" based on the law of La Place: mass = 4 x radius3. The Batista procedure thus determines how much muscle tissue to excise based on the ratio of mass relative to the diameter of the heart. Gordon thus determines an overall size of the heart relative to an overall mass of the heart, but nowhere discloses, suggests or infers any steps, tools, or calculations used to determine the size of a specific chamber of the heart based on the overall heart size or mass. Further, while Gordon discloses improved mortality rates and other advantages to patients as a result of the Batista procedure, no mention is made in Gordon even with respect to how the muscle mass or heart diameter is measured or determined. Nor does Gordon mention the tools or techniques used in making such mass and diameter determinations. While the Office Action intimates that the Batista procedure disclosed in Gordon are inherently performed and thus disclosed or suggested in Gordon, nothing in Gordon, or the Batista procedure discussed therein, suggests mentally visualizing or otherwise imaging or physically gauging the size of a specific chamber of the heart. Rather, Gordon discloses only that the Batista procedure determines the proportion of the mass of the heart to the diameter of the heart. Nothing further is disclosed in Gordon. Neither Gordon, nor the Batista procedure as discussed in Gordon, suggests that the

determination of a mass:diameter ratio of the heart overall is the equivalent of a size or volume determination of a specific chamber, i.e., a left ventricle, of the heart as contemplated in each of Applicants' independent claims 22, 31 and 38, which is prone to more accuracy than the mental "visualizing" or other "imaging" the Office Action suggests Gordon inherently discloses. Moreover, one skilled in the art would not equate the determination of a mass:diameter ratio, as in the Batista procedure, to a determination of a size of a specific chamber, i.e., left ventricle, of the heart. Rather, the mass:diameter ratio that is determined in the Batista procedure is used to determine how much muscle to excise so as to more closely approximate the preferred heart muscle mass to diameter ratio, i.e, not how to determine what the size of the left ventricle, or any specific chamber of the heart, is. Gordon thus fails to disclose or suggest gauging or determining the size of a left ventricle, or using an expansible member introduced into a left ventricle, to determine how much to reduce a volume or dimension of the left ventricle, as recited in Applicants' independent claims 22, 31 and 38, from one of which all remaining claims directly or indirectly depend.

In the Office Action, Gordon is further applied in combination with Kress and Hinnenkamp for rejecting claims 4, 5 and 10-12 (understood as corresponding to claims 25, 26 and 31-33, respectively). Kress discloses a method of sizing and implanting breast implants using a balloon 6 filled with fluid until a desired size is achieved, and then using that volume of liquid as the guide for making a precisely measured breast implant subsequently inserted into the breast cavity (col. 3, lines 11-12 and 28-40). Hinnenkamp discloses an adjustable sizing apparatus 10 for measuring the annulus 16 of anatomical tissue, such as the heart 18 to correlate a prosthetic heart valve with the tissue annulus 16 in order to ensure that the correct size heart valve is implanted in a patient (col. 3, line 65 – col. 4, line 8). Thus, neither Kress nor

Hinnenkamp overcomes the deficiencies of Gordon with respect to gauging or determining the size of a left ventricle, or using an expansible member introduced into a left ventricle, to determine how much to reduce a volume or dimension of the left ventricle, as recited in Applicants' independent claims 22, 31 and 38, from one of which all remaining claims directly or indirectly depend. Nor is there any motivation to combine Kress or Hinnenkamp with Gordon as Kress is for measuring breast tissue cavity without regard for the mass:diameter ratio thereof as in the Batista procedure discussed in Gordon, and Hinnenkamp is for measuring a tissue annulus for appropriately sizing a prosthetic valve without regard for the heart mass:diameter ratio of the Batista procedure discussed in Gordon. Moreover, the cancellation of claims 4, 5 and 10-12 renders any rejection thereof moot. Accordingly, withdrawal of the rejection of claims 4, 5 and 10-12 (or of respectively corresponding claims 25, 26 and 31-33 to the extent intended) based on the combination of Gordon, Kress and Hinnenkamp is respectfully requested.

In the Office Action, claims 13-16 and 18-21 (understood as corresponding to claims 34-37 and 39-42) are rejected based on the Batista procedure discussed in Gordon. Claims 13-16 and 18-21 have been cancelled, rendering moot any rejection thereof. Moreover, to the extent that this rejection is intended to reject the respectively corresponding claims 34-37 and 39-42, the Batista procedure as discussed in Gordon is discussed above as it relates to independent claims 31 and 38, from which claims 34-37 and 39-42 respectively depend. Gordon and the Batista procedure discussed therein, in combination with no other reference, fails to overcome the deficiencies thereof as discussed above with respect to independent claims 31 and 38, from which claims 34-37 and 39-42 respectively depend. Accordingly, withdrawal of the rejection of

claims 13-16 and 18-21 (or respectively corresponding claims 34-37 and 39-42 to the extent intended) is respectfully requested.

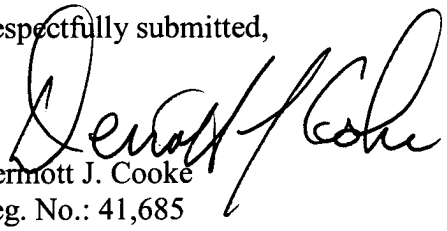
In the Office Action, claim 17 (understood as corresponding to claim 38 is rejected based on the combination of Gordon and Berman. Claim 17 has been cancelled previously, rendering any rejection thereof moot. Gordon is discussed above with respect to claim 38. Berman discloses a circumferential waist measuring device 10 for measuring the waist of an individual via an adjustable loop 14 attached to a main body 12 of the device 10. Berman thus fails to overcome the deficiencies of Gordon with respect to gauging or determining the size of a left ventricle, or using an expansible member introduced into a left ventricle, to determine how much to reduce a volume or dimension of the left ventricle, as recited in Applicants' independent claim 38. Nor is there any motivation to combine Berman with Gordon as Berman measures an individual's waist without regard for the mass:diameter ratio of a heart as in the Batista procedure discussed in Gordon. Accordingly, withdrawal of the rejection of claim 17 (or of corresponding claim 38, to the extent intended) based on the combination of Gordon and Berman is respectfully requested.

Notwithstanding any assertions to the contrary set forth in the Office Action, Applicants maintain that support for "gauging the size of the left ventricle" is amply supported in U.S. Patent No. 6,125,852 (U.S. Patent Application Serial No. 08/685,262, filed July 23, 1996), as agreed in the Interview held December 8, 2005, to which priority in the pending application is claimed.

Applicants respectfully submit, therefore, that all claims recite patentable subject matter. Reconsideration of the application and a prompt indication of the allowability of the claims is thus respectfully solicited. If the Examiner determines that anything further is desirable to place

this application in even better form for allowance, the Examiner is invited to contact the undersigned at his earliest convenience.

Respectfully submitted,



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